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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,374	06/13/2007	Robert Kenyon	F2010-7000US	9446
37462 7590 10/07/2009 LANDO & ANASTASI, LLP ONE MAIN STREET, SUITE 1100 CAMBRIDGE, MA 02142				
EXAMINER CHOI, FRANK I				
ART UNIT		PAPER NUMBER		
1616				
NOTIFICATION DATE		DELIVERY MODE		
10/07/2009		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@ll-a.com  
gengelso@ll-a.com

# Office Action Summary

**Application No.**

10/594,374

**Applicant(s)**

KENYON ET AL.

**Examiner**

FRANK I. CHOI

**Art Unit**

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SE-08)
- Paper No(s)/Mail Date 1/31/2007
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date \_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_

**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 18 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

*The nature of the invention:*

The invention is directed to a method of preventing an infection in a subject with the electrochemically activated water.

*The state of the prior art and the predictability or lack thereof in the art:*

The prior art discloses treatment of injections but not prevention. As such, prevention of infection appears to be of low predictability.

*The amount of direction or guidance present and the presence or absence of working examples:*

The Specification does not provide evidence showing that the composition is effective in preventing infection.

*The breadth of the claims and the quantity of experimentation needed:*

The claim is broad in that it claims prevention of infection. An infection occurs as soon as an microbe invades a cell, however, symptoms of an infection may not arise until latter. Thus,

an infection will already be present before action can be taken. Further, the term "prevention" includes within its scope that the person will never have an infection over their lifetime. As such, one ordinary skill in the art would have to do undue experimentation in order to show that the electrolytically activated water would be effective in preventing infection.

***Claim Rejections - 35 USC § 102/103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The claims are directed to electrolytically activated water having a chlorine content of not more than 8 ppm and methods for disinfection using the same.

Claims 1, 2, 5, 6, 11, 13, 15, 16, 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by McCallum (US Pat. 4,085,028).

McCallum expressly discloses electrolytically treating an aqueous sodium chloride solution where the amount of sodium chloride is 1000 ppm and the production of drinking water having 0.2 to 2 ppm of active chlorine and using 5.6 amps to electrolyze the water (Column 13, Column 17, lines 1-24, Column 20, lines 45-60).

Claims 1-17, 19-26 are rejected under 35 U.S.C. 103(a) as unpatentable over McCallum (US Pat. 4,085,028) in view of JP 05343252 and JP 08-089563.

McCallum discloses electrolytically treating an aqueous sodium chloride solution where the amount of sodium chloride is 1000 ppm and the production of drinking water having 0.2 to 2

ppm of active chlorine and using 5.6 amps to electrolyze the water (Column 13, Column 17, lines 1-24, Column 20, lines 45-60).

JP 05343252 disclose the sterilization of an endoscope with alkaline and acidic water produced by electrolysis of brine (Abstract).'

JP 08-089563 disclose a method sterilizing microorganisms a solution having a redox potential equal or greater than 820 mV, a dissolved chlorine concentration of 1 to 200 ppm, a dissolved oxygen concentration of 50 ppm or less (Abstract).

McCallum discloses electrolytically treating an aqueous sodium chloride solution where the amount of sodium chloride is 1000 ppm and the production of drinking water having 0.2 to 2 ppm of active chlorine and using 5.6 amps to electrolyze the water. The difference between McCallum and the claimed invention is that McCallum does not expressly disclose treatment of medical devices, a redox potential of at least 900 mV, and a dissolved oxygen concentration of between 11 and 17 mg/l or between 13 and 20 mg/l. However, the prior art amply suggests the same JP 05343252 disclose the sterilization of an endoscope with alkaline and acidic water produced by electrolysis of brine and JP 08-089563 disclose a method sterilizing microorganisms a solution having a redox potential equal or greater than 820 mV, a dissolved chlorine concentration of 1 to 200 ppm, a dissolved oxygen concentration of 50 ppm or less. As such, one of ordinary skill in the art would expected activated electrolysis waters having redox potentias and oxygen concentrationsl falling within the claimed ranges would be effective sterilants, including for medical devices.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

### *Conclusion*

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Wednesday and Thursday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi  
Patent Examiner  
Technology Center 1600  
October 6, 2009

/Johann R. Richter/  
Supervisory Patent Examiner, Art Unit 1616